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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/733,161	12/08/2000	Cameron G. Rouns	BAL-36	2368

7590 10/07/2003

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EXAMINER	
LAM, ANN Y	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 10/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/733,161	ROUNS ET AL.	
	Examiner	Art Unit	
	Ann Y. Lam	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 July 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 1-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Onohara et al., 4,834,721, in view of Becker et al., 4,198,983.

Onohara et al. discloses the invention substantially as claimed. Onohara et al. discloses a tube (i.e., catheter, see column 9, line13, and lines 27-29), and an anchoring means (i.e., balloon, or alternatively balloon and part of catheter, see column 9, line 13) mounted on the tube capable of retaining said feeding tube within the stomach wherein said anchoring means has at least one internal retaining member comprised of a modified silicone elastomer, see column 9, lines 12-15.

However, Onohara et al. does not disclose that the retaining member comprises the specific modified silicone materials claimed.

Onohara et al. however does disclose that a catheter tube and balloon can be made of the same silicone rubber for strong bonding, enabling wide and flexible selection for material combination of tube main body and balloon, see column 9, lines 12-29.

Furthermore, Becker discloses a catheter (10) comprised of a modified silicone elastomer, see column 2, lines 16-30, and column 3, lines 11-16, and column 5, line 58 – column 6, line 4. More specifically, Becker discloses a catheter formed from silicone elastomer comprised of materials as described below.

As to claims 2, 3 and 9, the modified silicone elastomer is trifluoropropylsiloxane modified dimethylpolysiloxane,

As to claim 4, said modified silicone elastomer is a diphenylsiloxane modified dimethylpolysiloxane, see column 3, lines 11-15.

As to claim 5, the trifluoropropylsiloxane is from about 5 to 95 mole percent, see column 2, lines 25-30 and lines 63-65.

As to claim 6, the trifluoropropylsiloxane is from about 40-60 mole percent, see column 2, lines 25-30 and 63-65.

As to claims 7 and 10, the diphenylsiloxane content is from .5 to 50 mole percent, see column 2, lines 25-30 and lines 63-65.

As to claim 8 and 11, the diphenylsiloxane content is from about 10 to 25 mole percent, or is less than about 2 mole percent, see column 2, lines 25-30 and lines 63-65.

As to claims 12, the modified silicone elastomer is endcapped with a material dimethylvinylsiloxane groups, see column 2, lines 36-43, lines 54-55, and column 5, lines 23-30.

As to claim 13, the retaining member is comprised of a fluoro modified polysiloxane, see column 3, lines 11-16.

As to claim 14, said fluoro modified polysiloxane comprises a trifluoropropylsiloxane modified dimethylpolysiloxane, see column 3, lines 11-16.

As to claim 15, said polysiloxane comprises a dimethylpolysiloxane, see column 2, lines 38-43.

As to claim 16, the fluoro modified polysiloxane contains from about 40 mole percent to about 60 mole percent fluoro groups, see column 2, lines 25-30 and lines 63-65.

As to claim 17, the fluoro modified polysiloxane contains trifluoropropylsiloxane in an amount from about 40 mole percent to about 60 mole percent, see column 2, lines 25-30 and lines 63-65.

As to claim 18, the fluoro modified polysiloxane is endcapped with a material dimethylvinylsiloxane groups, see column 3, lines 11-16.

As to claim 19, said fluoro modified polysiloxane contains a filler, see column 2, line 32.

As to claim 20, retaining member is comprised of a phenyl modified polysiloxane, see column 3, lines 11-16.

As to claim 21, the phenyl modified polysiloxane comprises a diphenylsiloxane modified demethylpolysiloxane, see column 3, lines 11-16.

As to claim 22, said polysiloxane comprises dimethylpolysiloxane, see column 3, lines 11-16.

As to claim 23, said phenyl modified polysiloxane contains diphenylsiloxane groups in an amount less than about 2 mole percent, se column 2, lines 25-30.

As to claim 24, said phenyl modified polysiloxane contains phenyl groups in an amount less than about 2 mole percent, see column 2, lines 25-30.

As to claim 25, the phenyl modified polysiloxane is endcapped with a material dimethylvinylsiloxane groups, see column 2, lines 36-43, and column 3, lines 11-16.

As to claim 26, said phenyl modified polysiloxane contains a filler, see column 2, line 32.

Since Onohara et al. teaches that a catheter tube and balloon can be made of the same silicone rubber for strong bonding, enabling wide and flexible selection for material combination of tube main body and balloon, and Becker teaches a catheter made from silicone elastomer with the specific claimed materials, it would have been obvious to one of ordinary skill in the art at the time the invention was made to form a catheter and balloon with the same silicone rubber, comprising the specific materials taught by Becker, for strong bonding between the catheter and balloon, as taught by Onohara et al..

2. Claims 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Miyata et al., 5,439,443, in view of Joh et al., 4,604,412.

Miyata et al. disclose a tube (i.e., catheter, see column 1, line 23, and column 2, line 27) and an anchoring means (i.e., balloon, see column 1, line 23, and column 2, line 26) mounted on the tube capable of retaining said feeding tube within the stomach.

Miyata et al. discloses that the balloon is comprised of polydimethylsiloxane (see column 1, line 36.)

However, Miyata et al. does not disclose that the anchoring means has at least one internal retaining member comprised of a modified silicone elastomer selected from the group consisting of phenyl-modified silicone, fluoro-modified silicone, and combinations thereof.

Joh discloses a blood-contact medical device such as a catheter (see column 1, lines 17-18) comprised of polydimethylsiloxane (see column 1, lines 36-37), similar to Miyata et al. (see above.) Joh further discloses that the polydimethylsiloxane develops antithrombogenic properties desirable for blood-contact medical devices (see column 1, lines 28-31.) Joh also further teaches a composition that develop better antithrombogenic material, see column 1, lines 38-51.) Joh discloses that this composition may include diphenylsiloxane (see column 3, line 30.)

Thus, since Miyata et al. teach that a medical balloon can be comprised of polydimethylsiloxane, and Joh discloses blood-contact medical devices comprised of polydimethylsiloxane, and Joh further teaches that a substitute material comprised of diphenylsiloxane develops better antithrombogenic properties desirable for blood-contact medical devices, it would have been obvious that the Miyata et al. polydimethylsiloxane can be substituted with diphenylsiloxane composition taught by Joh in order to develop better antithrombogenic properties.

Response to Arguments

Applicant argues that although Becker et al. teaches that the shaft can be made from a thermoplastic material containing as one ingredient a cross-linked organic silicone elastomer, it nonetheless teaches that the balloon itself is made from a mixture of block polymers and mineral oil (see page 7 of Applicant's arguments.) Applicant also argues that the references fails to provide a motivation to combine the references.

To further elaborate on the rejection above, Examiner asserts that Miyata et al. discloses that a catheter tube and balloon may each be made of a same silicone rubber material (see column 9, lines 12-15). Becker also discloses diphenylsiloxane as a silicone material known to be used in forming catheters (see column 3, lines 12-13 of Becker.) Thus, since Onohara et al. teaches that a catheter shaft and balloon may each be made of the same silicone rubber material, and Becker teaches diphenylsiloxane as a known silicone materials used in forming catheters, it would have been obvious to form the Onohara et al. catheter and balloon from the diphenylsiloxane material as taught by Becker as the silicone rubber material.

Alternatively, since Applicant has not clearly defined what comprises the internal retaining member, part of the catheter disclosed by Onohara et al. is considered to be part of the internal retaining member. Thus, since Onohara teaches that a catheter may be made of a silicone rubber, and Becker teaches that a catheter can be made of diphenylsiloxane, it would have been obvious to provide diphenylsiloxane as the silicone rubber used to form the Onohara et al. catheter.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is (703) 306-5560. The examiner can normally be reached on M-Sat 11-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (703)305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0196.

A.L.

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

10/06/03